

Cosmo's licensee in the US Santarus receives FDA approval of UCERIS™ for the induction of remission in patients with active, mild to moderate ulcerative colitis

Lainate, Italy – January 15, 2013 – Cosmo Pharmaceuticals, (SIX:COPN) today announced that its licensee in the USA, Santarus (NASDAQ:SNTS) announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for UCERIS™ (budesonide) extended release tablets for the induction of remission in patients with active, mild to moderate ulcerative colitis. Santarus expects the commercial launch of UCERIS to begin in March 2013.

UCERIS™ contains budesonide, a corticosteroid, in a novel oral tablet formulation that utilizes proprietary MMX® multi-matrix system colonic delivery technology. The approved dosing regimen for adult patients is one 9 mg tablet taken orally once daily in the morning for up to 8 weeks. UCERIS™ was developed in collaboration with Cosmo Technologies Limited, a subsidiary of Cosmo Pharmaceuticals S.p.A.

"The FDA approval of UCERIS™ provides an important new therapeutic option to patients and physicians for the treatment of active, mild to moderate ulcerative colitis," said William J. Sandborn, M.D., chief, division of Gastroenterology, director, University of California San Diego (UCSD) IBD Center and professor of clinical medicine, UCSD Health System. "Specifically, UCERIS™ is indicated for use in the induction of remission of active disease, an acute phase of the disease often characterized by cramping, bloating, diarrhea, bleeding, fatigue, weight loss and frequent bowel movements."

Mauro Ajani, Chairman and CEO of Cosmo Pharmaceuticals SpA, the parent of Cosmo Technologies Ltd said: "This approval documents the versatility of the MMX technology for colonic applications. Uceris™ is the only corticosteroid approved for treatment of patients with active mild to moderate ulcerative colitis in the USA. We are very pleased to have contributed to US patients' now having an important treatment option".

About Ulcerative Colitis

Ulcerative colitis is a form of inflammatory bowel disease (IBD) that produces inflammation and ulcers along the inside of the colon. The inflammation can interfere with the normal function of the colon, often causing cramping, bloating, diarrhea, bleeding, fatigue, weight loss and frequent bowel movements, which may also strongly affect quality of life. It is believed that as many as 0.7 million people in the U.S. and as many as 0.9 million people in the EU have Ulcerative Colitis.

Ulcerative Colitis is a chronic relapsing-remitting illness for which there is no known cure, but with appropriate treatment patients can manage their symptoms. However, it is estimated that up to 30% of patients with mild or moderate ulcerative colitis do not respond to aminosalicylate (5-ASA) drugs and require a different or add on therapy. Patients refractive to treatment with 5-ASA drugs typically receive a course of a systemically absorbed corticosteroid, the success of which may be limited by

significant side effects. For moderate to severe cases of ulcerative colitis, immunosuppressant drugs or biologic drugs may be prescribed. If the condition does not respond to pharmaceutical therapy and the symptoms are severe, the patient may be referred for surgery.

About Cosmo Pharmaceuticals

Cosmo is a speciality pharmaceutical company that aims to become a global leader in the field of optimized therapies for selected Gastrointestinal and topically treated Skin Disorders. The company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, such as Ulcerative Colitis and Crohn's Disease, and Colon Infections. In addition, the Company is developing a diagnostic for the detection of colon cancer and a new chemical entity for the topical skin treatment. Cosmo's first MMX® product that has reached the market is Lialda®/Mezavant®/Mesavancol®, a treatment for IBD that is licensed globally to Giuliani and Shire Limited. Cosmo's proprietary MMX® technology is at the core of the Company's product pipeline and was developed from its expertise in formulating and manufacturing gastrointestinal drugs for international clients at its GMP (Good Manufacturing Practice) facilities in Lainate, Italy. The technology is designed to deliver active ingredients in a targeted manner in the intestines. For further information on Cosmo, please visit the Company's website: www.cosmopharma.com

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Dr. Chris Tanner, CFO and Head of Investor Relations

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Some of the information contained in this press release contains forward-looking statements. Readers are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors. Cosmo undertakes no obligation to publicly update or revise any forward-looking statements.

REDACTED IN ITS ENTIRETY

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.À R.L.,))))
Plaintiffs,) C.A. No. 15-669-LPS
v .)
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,)))
Defendants.)
DECLARATION OF ROBE	PRTA ROZZELLA
I, Roberta Bozzella declare as follows:	INTER DO EDISCULA
I am currently employed by Cosmo Sp	A, an affiliate of Cosmo Technologies Ltd.
("Cosmo") and have been employed by Cosmo since.	January 7, 2002. Unless otherwise stated, I
have personal knowledge of the matters set forth here	in, and if I am called upon to testify, I
could testify competently thereto.	
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- 6. Based on my time as a Cosmo employee and on my experiences attending meetings like the one identified in Cosmo would not have shared information regarding the MMX formulation technology with outside consultants without an understanding that the information would be kept confidential.
 - 7. Uceris® employs MMX formulation technology.
- I declare under penalty of perjury under the laws of the United States of America
 that the foregoing is true and correct.

Executed on October 13, 2016 in Lainate, Italy.

Roberta Bozzélla

Graham Buckton

BPharm, AKC, C.Dir, PhD, DSc, CChem, FRSC, FAPS, FAAPS, FRPharmS

1) Personal Details

Name: Graham Buckton Date of Birth: 30.4.60 Status: Married, 2 children

Nationality: British Born: Brighton, Sussex.

2) Fellowship/Membership of Professional Bodies/Associations:

The Royal Pharmaceutical Society of Great Britain made a Fellow in April 1997; The Royal Society of Chemistry made a Fellow in 1997; American Association of Pharmaceutical Scientists made a Fellow in 1997; Academy of Pharmaceutical Sciences made a Fellow in 2009. Member of MENSA. (lapsed)

Associations/Clubs – The Athenaeum. The Worshipful Society of Apothecaries. MCC. North Hants Golf Club.

3) Awards/Honours

2012 Freedom of the City of London.

2003 Science Chairman for the British Pharmaceutical Conference.

2000 First recipient of the Academy of Pharmaceutical Sciences Medal, for services to UK Pharmaceutical Sciences (relating to the establishment of the APS by negotiating a merger between the previously competing activities of "UKAPS" and the "Pharmaceutical Sciences Group").

1998 Stig Sunner Award, presented by the USA Calorimetry Conference "in recognition of research and contributions to thermodynamics and thermochemistry" to a scientist under the age of 40.

1998 Foss Near Infra red European Users Group award for best new work in near-IR spectroscopy

1993 British Pharmaceutical Conference Science Medal

1992 Pfizer Award for "excellence in published research", granted for "imaginative use of thermodynamic principles in the understanding and design of drug delivery systems". The Pfizer Awards are not open to application, and are given on the basis of review of published literature by senior Pfizer scientists, and senior academic advisers

4) Education

Institute of Directors2012 Diploma in Company Direction

Institute of Directors 2012 Certificate in Company Direction.

University of London 1997 Doctor of Science for research work in pharmaceutical materials science.

King's College (KQC), University of London, Manresa Road.

September 1982 - August 1985 <u>**Ph.D.**</u> Title: Assessment of the wettability of powders 1985-1987 <u>Associate of King's College</u> (AKC) Examined course in Philosophy (part time)

Chelsea College, University of London, Manresa Road.

September 1978 - June 1981. <u>**B.Pharm.**</u> (Hons.)

Varndean Sixth Form College, Brighton, Sussex.

September 1976 - July 1978; AO level - Human Biology; 3 A levels - Mathematics, Chemistry and Physics.

Brighton Secondary Technical School.

September 1971 - July 1976, June 1975 3 O levels; June 1976 8 O levels

5) Present Employment

Managing Director of Buckton Consulting

Emeritus Professor of Pharmaceutics, UCL School of Pharmacy, University of London and

5.1) Academic

Research

I have an active research group and collaborate with colleagues to supervise research at UCL School of Pharmacy and Nottingham University

The work relates to materials science applied to pharmaceutical processing and drug delivery systems, notably those for inhalation and oral delivery. Further details are presented below.

Examining:

Chair of the MPharm exam board (2002-2012)

Past-chair of the exam boards for MSc subjects.

Numerous PhD degrees (in recent years venues in clude: LSOP, Kings College London, Imperial College, Nottingham, Cardiff, Bradford, Brighton, Portsmouth, Manchester, Aston, Grenwich, Canterbury, Uppsala (Sweden), Copenhagen, Oslo).

I have been / am MPharm examiner at Queens University of Belfast, Cardiff, Nottingham, Kings College, University of Colombo, Sri Lanka, and Robert Gordon University

Previously MSc examiner Kings College London and MSc Industrial Pharmacy, University of Brighton.

5.2 Buckton Consulting (a part of Brighton City Property Ltd)

Consultancy service covering:

- 1) pharmaceutical physical form, formulation development, GMP manufacturing and regulatory considerations.
- 2) Company strategic review and management
- 3) Due diligence
- 4) Expert witness

I act as a consultant to industrial companies in UK, mainland Europe, middle east and USA. This is a diverse role involving advice on materials science, formulation (inhalation and oral products), regulatory, and as an expert witness in patent litigation.

6) Previous employment

Pharmaterials Ltd

I founded Pharmaterials Ltd in 2000 to transfer advanced materials characterisation techniques into a commercial contract service. I developed the company to cover preformulation, especially salt and polymorph selection, formulation development (oral and inhalation) and GMP clinical trial manufacture in a large purpose built facility in Reading UK. The % of my time linked to this activity expanded (to 70%) to keep pace with the needs of the success of a growing enterprise.

Pharmaterials operates on a fee for service basis and has grown through profits on income.

Pharmaterials won the Queen's Award for Enterprise in 2008 for international trade.

At the time of my departure 36 staff were employed.

In keeping with the success of the business, the majority stake in Pharmaterials was sold to PII in January 2008. The remaining stake was sold in September 2012 at hich stage I exited from my role as Chief Executive of the company, where I acted to directly oversee the strategic and business planning, financial management, business development, staffing and resource provision.

School of Pharmacy, University of London, 29-39 Brunswick Square, London WC1N 1AX 1988 - 2015

January 2001 – April 2007 <u>Head of Department of Pharmaceutics</u>.

Management and Leadership

Of the School

As Head of Department much of my time was spent discussing the management of the School, including preparations for previous and future research assessment exercise, teaching quality audit, day-to-day management and strategic directions.

Internal committees:

Member of <u>School Council</u>. Member of the following committees of Council: Finance, Nominations, Governance, Fellowship and Honorary Degrees, Audit Committee.

<u>Other School Committee work</u>: Academic Board, Policy and Resources Executive, Policy and Resources, Research Strategy Task Force, Academic Standards, Undergraduate Studies Management Group, Pharmacy Advisory, Library and Information Services, Joint Committee of Academic Board and Students, Higher Degrees, Taught Postgraduate Studies.

Of the Department of Pharmaceutics

Pharmaceutics had 13 fte academic staff, and some 70 research staff/PhDs, also 5 technicians, and support services (workshop and wash-up). In my time as Head all bar 1 member of academic staff was either appointed or promoted.

I managed the staff development and infrastructure for the departmental activities, to maximise the productivity, whilst working within strict financial limits.

I appointed senior industrialists to positions of visiting professor to develop strategy for direction and funding.

Teaching:

Instigator of MSc in Drug Delivery (developed concept and course, then transferred to staff to manage)

Provide direction for all teaching in Pharmaceutics through regular reviews with staff, informed by staff views and course review reports. Allocate staff to lead the Pharmaceutics teaching in each semester, manage projects and dissertations, and the examination processes.

I was part of the small design team that initiated the review of the BPharm, to produce a matrix management teaching structure (of course coordinators and heads of departments) to allow better subject integration. I was part of the group that assigned subjects to semesters and planned the curriculum, I was one of the first course coordinators. This structure was expanded to form the basis of the existing MPharm.

Previous positions at the School of Pharmacy, University of London

July 1998 Professor of Pharmaceutics;

May 1995 Reader in Pharmaceutics;

February 1991 Senior Lecturer in Pharmaceutics;

September 1988 Lecturer in Pharmaceutics;

Lecturer in Pharmacy (Pharmaceutics)

Chelsea Department of Pharmacy, King's College (KQC), University of London, Manresa Road, London, SW3 6LX.

October 1984 - September 1988

Advanced Drug Delivery Research unit, Ciba-Geigy Pharmaceuticals, Horsham.

July to December 1987 (Secondment)

Charing Cross Hospital, Fulham Palace Road, London.

August 1981 - July 1982. Pre-registration pharmacist

Community Pharmacy Locum work (1982-1988)

7) External activities

Currently

Member of the Chemistry, Pharmacy and Standards Subcommittee of CHM (2005-)

Member of the United States Pharmacopoeia Expert Group on Physical Methods (20010-)

Steering Committee of The Handbook of Pharmaceutical Excipients

Editorial Board of Recent Patents on Drug Delivery and Formulation. Advances in Pharmaceutics.

Previously:

British Pharmacopoeia Commissioner (2004-2010)

Member of the BP committee on pharmacy (2005-2012)

Member of a European Pharmacopoeia Working Party (2008-2010)

Member of Committee on Safety of Medicines until it was disbanded in 2005.

Chairman of Chemistry, Pharmacy and Standards sub-committee of CSM and member of this committee previously.

Editor of International Journal of Pharmaceutics (1999-2009)

Editorial board member of: Pharmaceutical Research, The AAPS Journal, AAPS PharmSci Tech

Course organiser for RPSGB residential meeting on "Tabletting Technology" (Every year 1989 - 2004)

Member of the Committee of the Pharmaceutical Sciences Group of the Royal Pharmaceutical Society, now the Academy of Pharmaceutical Sciences (1994 - 2001)

Chairman of the RPSGB Pharmaceutical Sciences Group (1995-7).

Member of the RPSGB Science Committee and also British Pharmaceutical Conference Committee (during period 1995-2003)

Chairman for 1997 AAPS/RPSGB Arden House Conference (Europe). Faculty member for Arden House USA.

Member of IUPAC Commission on Thermodynamics task group - Calibration of calorimeters.

The first Chairman of the Academy of Pharmaceutical Sciences of Great Britain (1999-2000).

Chairman for the 2005 AAPS/APS/RPSGB Arden House Conference (Europe), Planning committee Arden House USA. (First person to have chaired this prestigious meeting twice).

Course organizer / Planning Committee member for numerous international conferences across Europe.

8) Research

The central theme of my research is to investigate the behaviour of materials of pharmaceutical importance in terms of their molecular and interfacial properties and to relate such behaviour to processing and drug delivery.

Current work is diverse in application, ranging from fundamental studies on surfaces, through the adaptation of physical properties of powders by crystallisation and physical manipulation (e.g. milling), to the preparation and characterisation of dosage forms (solid oral / inhalation). A major part of my work centres on investigations of powder / water interactions. The implications of powder / water interactions are manifold, influencing many aspects, including product (solid and liquid dosage forms) preparation, usage (e.g. drug release), and stability (microbiological, chemical and physical). With such diverse applications, the scope of this research grows with each experiment, new avenues are constantly discovered.

8.1) Grants obtained

- 1987 Glaxo Group Research fully funded PhD student (Effect of processing and chemical structure on surface energetics) ca £25,000.
- 1987 Ciba-Geigy Advanced Drug Delivery Research fully funded PhD student (Binding of opsonising proteins to drug conjugates) ca£23,000.
- 1987 Glaxo Group Research £2,500 to purchase equipment.
- 1987 Lilly Research Ltd. Gift of computing equipment (value £6,000).
- 1988 Wellcome Foundation Ltd. £10,000 for equipment.
- 1988 Wellcome Foundation Ltd. £1,000 for work on surface energetics of polymorphs.
- 1988 Wellcome Foundation Ltd. Fully funded PhD student (Crystal engineering and surface energetics) ca£23,000.
- 1988 SERC CASE Lilly Research Centre Ltd. PhD student, The stability of inhalation aerosols, plus ongoing gifts of equipment ca £28,000.
- 1988 Upjohn Ltd. Summer studentship £1000.

- 1988 Wellcome Foundation Ltd. Summer studentship £1000.
- 1988 Lilly Research Centre Ltd, Two summer studentships £2000.
- 1988 Wellcome Foundation Ltd., Fully funded PhD student £25,000
- 1988 SERC/ CASE award with Beecham Pharmaceuticals, £25,000
- 1989 Wellcome Foundation Ltd. £1,876 towards equipment.
- 1989 Wellcome Trust Summer Studentship £622
- 1989 Lilly Research Summer Project (£750)
- 1990 British Council Travel Award to visit University of Athens (£2800).
- 1990 SERC/CASE award with MSD, Computer modelling as a means of predicting powder properties. £30,000
- 1991 The Wellcome Trust, £29,639 to purchase a microcalorimeter.
- 1992 The Wellcome Foundation £33,000 for PhD studentship
- 1992 Thermometric Ltd. £12,000 of calorimetric equipment.
- 1993 The Wellcome Foundation Ltd. £15,000 for employment of a research Technician.
- 1993 School of Pharmacy studentship for PhD studies, with collaborative funding obtained from MSD (£30,000).
- 1993 SERC/CASE award with MSD (£30,000.
- 1993 The Wellcome Trust, Characterisation of powder surface properties, with application to inhaled drug delivery, £100,515
- 1994 Roche Products Ltd., Surface properties of powders in relation to tabletting. ca £40,000 over 3 years.
- 1994 EPSRC ROPA award (the first of such awards to be made), £47,940 for the purchase of a microcalorimeter.
- 1994 The Wellcome Foundation, £750 towards maintenance of the microcalorimeter.
- 1994 Pharmacia Farmitalia, £4,000 towards the cost of a project on bioadhesion.
- 1994 SERC/CASE award, SB Pharmaceuticals molecular structure, crystal packing and physico-chemical properties of drugs.(£40,000)
- 1994 Wellcome Foundation, gift of equipment and software for instrumentation of atabletting machine ca £10,000..
- 1995 Merck, West Point, USA, £43,000 over 3 years to study drug-surfactant interactions.
- 1995 Pfizer Central Research, £43,000 over 3 years to study powder mixing.
- 1995 SB Pharmaceuticals, industrial CASE allocation, to study spray granulation.
- 1996 Glaxo-Wellcome, £43,500 over 3 years to study microfluidisation technologies.
- 1996 Mendell ca £21,000 for studies on microcrystalline cellulose.
- 1997 Astra Charnwood £45,000 over 3 years to study surfactant systems
- 1997 SB/Roche/Pfizer £190,000 over 3 years to develop inverse phase gas chromatography
- 1997 EPSCR/MSD Case project ca £45,000 over 3 years to study drying processes.
- 1997 Mendell £25,000 for further studies on microcrystalline cellulose.
- 1997 Mendell £7,500 for calorimetry accessories.
- 1998 ICI, application of isothermal microcalorimetry £60,000
- 1998 Core Technologies, post-doctoral worker on hydrogel technology, ca £65,000
- 1998 Elan Pharmaceuticals, post-doctoral worker on surfactant systems, ca£65,000
- 1998 Pfizer Central Research, PhD on powder mixing, £50,000
- 1998 Industrial BBSRC/CASE award from SB pharmaceuticals, £50,000
- 1998 RPSGB Award to Sarah Hogan for PhD studentship, ca £45,000
- 1999 Novartis studies of dry powder inhaler design £69,000
- 1999 EPSRC CASE with SB Pharmaceuticals- powder surface charactersiation £48,000

2000 BBSRC committee student to study stabilisation of solid state macromolecules £60,000.

2001 EPSRC/GSK - £20,550 to fund study of Dynamic vapour sorption technique

2001 AstraZeneca - £50,000 to fund study on Modification of surfaces of microparticles for inhalation

2001 GSK - £20,550 to fund investigations into predicting physical stability of amorphous compounds

2001 EPSRC - £192,271 to fund study of preparation and characterisation of amorphous pharmaceutical blends from libraries of polymers

2001 Schering Plough - £50,000 The effect of milling process on crystalline materials.

2002 Pfizer Central Research £150,000 to fund Centre for Paediatric Pharmacy (with lan Wong)

2003 AstraZeneca – 45,000 First studentship rolling scheme.

2002 £4000 bench fee for visiting scientist (Dr Ohta from Japan)

2003 Meiji Seika Daisha Ltd – £7,000 Bench fee for visiting Scientist

2004 Pfizer Central Research £60,000 for PhD student on inhalation formulation.

2005 EPSRC Academic Fellowship Scheme, £125,000 for Solid state DNA vaccine particles for inhaled drug delivery. (5 year fellowship jointly funded by School), with Prof Alpar.

2005 BBSRC £50,000 for establishment of distance learning MSc in Drug Delivery.

2005 Astra Zeneca ca £60,000 for PhD student on the stability of pressurized metered dose inhalers

2006 Pfizer Central Research ca £80,000 for PhD student on Process Analytical Technology

2006 Maplethorpe post doctoral grant – surface energy determination using AFM and IGC c £80,000.

2012 EPSRC DTC with Uni of Nottingham, Pfizer, AZ, GSK and other £1,950,000.

2014 EPSRC DTC with Nottingham £11,800,000

8.2) Publications

8.2.1) Single authored book

Interfacial phenomena in drug delivery and targeting.

G.Buckton, Harwood Academic Press, Amsterdam, (1995). Part of the series in Targeting and Drug Delivery

8.2.2) Book

Pharmaceutical Thermal Analysis (2nd Edition) J Ford, P.Timmins and G.Buckton. (2001) Taylor and Francis.

8.2.3) Full Papers

- 1) Assessment of the wettability and surface-energy of a pharmaceutical powder by liquid penetration.
- G.Buckton and J.M.Newton, (1985), J. Pharm. Pharmacol., <u>37</u>, (9): 605-609.
- 2) The significance of contact angles measured on surfaces that have undergone plastic deformation.

- G.Buckton and J.M.Newton, (1986), in Gorrod, J.W., Gibson, G.G., and Mitchard, M., (Eds.), Development of Drugs and Modern Medicine, Ellis Horwood, Southampton, pp421-424.
- 3) Assessment of the wettability of powders by use of compressed powder discs. G.Buckton and J.M.Newton, (1986), Powder Technol., 46, (2-3): 201-208.
- 4) Liquid penetration as a method of assessing the wettability and surface energy of pharmaceutical powders.
- G.Buckton and J.M.Newton, (1986), J. Pharm. Pharmacol., 38, (5): 329-334
- 5) A vacuum microbalance technique for studies on the wettability of powders. G.Buckton, A.E.Beezer and J.M.Newton, (1986), J. Pharm. Pharmacol., <u>38</u>, (10): 713-720.
- 6) The potential value of dielectric response measurements in the assessment of the wettability of powders.
- G.Buckton, L.A.Dissado, R.M.Hill and J.M.Newton, (1987), Int. J. Pharm., 38, (1-3): 1-7.
- 7) A microcalorimetric study of powder surface energetics. G.Buckton and A.E.Beezer, (1988), Int. J. Pharm., <u>41</u>, (1-2): 139-145.
- 8) <u>In vitro</u> dissolution of some commercially available sustained release theophylline preparations.
- G.Buckton, D.Ganderton and R.Shah, (1988), Int. J. Pharm., 42, (1-3): 35-39.
- 9) Preservation of oral solid dosage forms.
- T.C.Blair, G.Buckton and S.F.Bloomfield, (1988), in Bloomfield, S.F., Leech,R., Baird,R. and Leak,R., (Eds.), Microbial Quality Assurance of Pharmaceuticals, Cosmetics and Toiletries, Ellis Horwood, Southampton, pp104-118.
- 10) Effect of comminution technique on the surface energy of a powder.

 G.Buckton, A.Choularton, A.E.Beezer and S.M.Chatham, (1988), Int. J. Pharm, 4
- G.Buckton, A.Choularton, A.E.Beezer and S.M.Chatham, (1988), Int. J. Pharm. <u>47</u>, (1-3): 121-128.
- 11) The assessment, and pharmaceutical importance, of the solid / liquid and the solid / vapour interface: a review with respect to powders. Invited review.
- G. Buckton, (1988) Int. J. Pharm., 44, (1-3): 1-8.
- 12) Structure-activity relationships for solubility and wettability of a number of substituted barbituric acids.
- G.Buckton and A.E.Beezer (1989) Thermochimica Acta., 138, (2): 319-326
- 13) <u>In vitro</u> dissolution testing of oral controlled release preparations in the presence of artificial foodstuffs. I) Exploration of alternative methodology: microcalorimetry. L.J.Ashby, A.E.Beezer and G.Buckton, (1989), Int. J. Pharm., 51, (3): 245-251.
- 14) <u>In vitro</u> dissolution testing of oral controlled release preparations in the presence of artificial foodstuffs. II) Probing drug / food interactions using microcalorimetry.
- G.Buckton, A.E.Beezer, S.M.Chatham and K.K.Patel, (1989), Int J Pharm., <u>56</u>, (2): 151-157.
- 15) The use of surface-energy values to predict optimum binder selection for granulations.

- L.Zajic and G.Buckton, (1990), Int. J. Pharm., <u>59</u>, (2): 155-164.
- 16) Contact-angle, adsorption and wettability a review with respect to powders. Invited review. G.Buckton, (1990), Powder Technol., <u>61</u>, (3): 237-249.
- 17) Modelling drug release from hydrophobic matrices by use of thermodynamic activation parameters.
- M.Efentakis and G.Buckton, (1990), Int. J. Pharm., 60, (3): 229-234.
- 18) Particle growth in aqueous suspension: the influence of surface-energy and polarity. S.A.Young and G.Buckton, (1990), Int. J. Pharm., 60, (3): 235-241.
- 19) Polyoxyethylene polyoxypropylene block copolymers: a novel phase transition in aqueous solution of Pluronic F87.
- N.Mitchard, A.E.Beezer, N.Rees, J.Mitchell, S.Leharne, B.Chowdhry and G.Buckton, (1990), J.Chem. Soc., Chem. Commun. (13): 900-901.
- 20) The use of thermodynamic activation parameters and compensation analysis to model drug release from hydrophobic matrices.
- G.Buckton and M.Efentakis, (1990), Int. J. Pharm., 62, (2-3): 157-163.
- 21) The interaction of various types of microcrystalline cellulose and starch with water. T.C.Blair, G.Buckton, A.E.Beezer and S.F.Bloomfield, (1990), Int. J. Pharm., 63, (3): 251-257.
- 22) The role of compensation analysis in the study of wettability, solubility, disintegration and dissolution.
- G.Buckton, (1990), Int. J. Pharm., <u>66</u>, (1-3): 175-182.
- 23) Problem based learning a valuable approach to pharmaceutical education. G.Buckton and I.P.Bates, (1991), Int. Pharm. J., <u>5</u>: 7-13.
- 24) Modelling drug release from matrix formulations by use of thermodynamic activation parameters and extrathermodynamics.
- G.Buckton, M.Efentakis and Z.Hussain, (1991), Eur. J. Pharm. Biopharm., 37, (3):154-158.
- 25) Solution thermodynamics of 4-hydroxybenzoates in water, 95 % ethanol / water, 1-octanol and hexane.
- A.E.Beezer, G.Buckton, S.Forster, W-B.Park and G.J.Rimmer, (1991), Thermochimica Acta, 178: 59-65.
- 26) Spreading coefficients: the practical application of surface energy and polarity data. Invited review.
- G.Buckton, (1991), Pharmakeftiki, 3: 145-149.
- 27) The influence of surfactants on drug release from a hydrophobic matrix.

 M.Efentakis, H.Al-Hmoud, G.Buckton and Z.Rajan, (1991), Int. J. Pharm., 70, (1-2): 153-158.
- 28) On the mechanism of kill of microbial contaminants during tablet compression. T.C.Blair, G.Buckton and S.F.Bloomfield, (1991), Int. J. Pharm., 72, (2): 111-115.

- 29) The effect of surface treatment on the values of contact angles measured on a compressed powder surface.
- I.O.Odidi, J.M.Newton and G.Buckton, (1991), Int. J. Pharm., 72, (1): 43-49.
- 30) The importance of chain-length on the wettability and solubility of organic homologs. S.Forster, G. Buckton and A.E.Beezer, (1991), Int. J. Pharm., 72, (1): 29-34.
- 31) Sustained release (SR) theophylline preparations: A review of biopharmaceutical influences on <u>in vivo</u> and <u>in vitro</u> drug absorption / release data. Invited review. G. Buckton, (1991), J. Biopharm. Sci., <u>2</u>: 81-96.
- 32) Pharmaceutical microcalorimetry: a selective review. Invited review. G.Buckton, S.Russell and A.E.Beezer, (1991), Thermochim. Acta, <u>193</u>: 195-214
- 33) The applications of microcalorimetry to the field of physical pharmacy. G.Buckton and A.E.Beezer, (1991), Int. J. Pharm., 72, (3): 181-191 (Invited review).
- 34) Surface analysis of pharmaceutical powders. I) X-ray photoelectron spectroscopy (XPS) related to powder wettability. G.Buckton, R.Bulpett and N. Verma, (1991), Int. J. Pharm., <u>72</u>, (2):157-162.
- 35) The influence of surfactants on drug release from acrylic matrices.

 G.Buckton, M.Efentakis, H.Al-Hmoud and Z.Rajan, (1991), Int. J. Pharm., 74, (2-3): 169-174.
- 36) Observations on the biopharmaceutical importance of chain-length in pharmaceutically related compounds.
- G.Buckton, A.E.Beezer, S.P.Denyer and S.J.Russell, (1991), Int. J. Pharm., 73, (1): 1-7.
- 37) NMR evidence for novel phase transition in aqueous solutions of pluronic-F87 (poloxamer 237).
- A.E.Beezer, J.C.Mitchell, N.H.Rees, J.K.Armstrong, B.Z.Chowdhry, S.Leharne and G.Buckton, (1991), J. Chem. Res. (9): 254-255.
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- 97) Measurement of molecular mobility of molecules in amorphous state using enthalpy relaxation data measured by StepScan DSC, A.V. Ambarkhane, B. Stockton and G Buckton. BPC, Harrogate 2003.
- 98) Estimation of critical relative pressure of water (%cRH) for amorphous indomethacin using Isothermal microcalorimetry. A.V. Ambarkhane, B. Stockton and G. Buckton. BPC, Harrogate 2003.
- 99) The use of inverse phase gas chromatography to study the glass transition temperature of a powder surface. A.V. Ambarkhane, K. Pincott and G. Buckton. BPC, Manchester 2004.
- 100) Calorimetric study of protein adsorption onto polystyrene latexM.J. Pollitt, G. Buckton, H.O. Alpar, S. BrocchiniPresented at the 5th European Workshop on Particulate Systems, London, July 2004.
- 101) Estimation of glass transition of amorphous lactose by inverse gas chromatography. A.V. Ambarkhane, K. Pincitt and G Buckton. AAPS, Baltimore 2004.
- 102) In vitro deposition from a dry powder inhaler and its correlation with surface energy of amorphous fine particle surfaces
- A.C. Oliveira, G. Buckton, E. Collins (need to check rest of names). (2006) J. Pharm. Pharmacol., <u>58</u>, (1): A24-A24
- 103) A calorimetric investigation of hydrogel swelling and drug release L. He, S. Gaisford, S. Conti (need to check rest of names). (2006) J. Pharm. Pharmacol., <u>58</u>, (1): A21-A22
- 104) In-situ process monitoring using calorimetry: Assessment of powder and tablet swelling S. Gaisford, S. Conti and G Buckton. (2006) J. Pharm. Pharmacol., 58, (1): A5-A5
- 105) The characterization and dissolution properties of griseofulvin solid dispersions with HPMCAS
- H. Al-Obaidi and G. Buckton. (2006) J. Pharm. Pharmacol., 58, (1): A18-A19
- 106) Bridging polymeric excipients to stabilise amorphous dispersionsJ. Fletcher, N. Wilson, G. Buckton, S. BrocciniSent to Controlled Release Society Meeting
- 107) Spray dried alkaline phosphatase: variation of particle morphologyA. Khalid, G. Buckton, S. BrocchiniSent to Controlled Release Society Meeting
- 108) Influence of the spray-drying concentration on the relaxation of an amorphous solid dispersion

H. Al-Obaidi, S. Brocchini, G. Buckton BPC, 2007

- 109) Variation of dissolution rate of spray-dried solid dispersions from different solvents H. Al-Obaidi, S. Brocchini, G. Buckton BPC, 2007
- 110) Comparison of particle-particle interactions measured by atomic force microscopy and calculated from Hansen solubility parameters measured by inverse gas chromatography: preliminary report. In proceedings of Drug Delivery to the Lungs 18, Edinburgh, UK, pp. 180-83. M.D. Jones and G. Buckton The Aerosol Society, 2007
- 111) Solution calorimetry: A valuable technique to investigate properties of co-crystals. M. Majumder, C. Rawlinson, A.C.Williams and G.Buckton. BACG meeting, London July 2011.
- 112) Producing homogeneous co-crystals in solid state: Can solution calorimetry provide kinetic information?

M.Majumder, C.F.Rawlinson, A.C Williams and G.Buckton UKPharmSci, August 2011.

113) Surface properties and aerosolization behavior of anhydrous and cocrystal forms of theophylline.

A.Alhalaweh, G.Buckton and S.P.Velaga. AAPS Annual Meeting, Washington DC, October 2011.

- 114) Mannitol as a co-milling agent for the preparation of theophylline inhalable particles. M Malamatari, S Somavarapu, M Bloxhamn G. Buckton. Pharmaceutical Technology conference, Croatia. 2015.
- 115) Understanding nanoscale order in amorphous pharmaceuticals. K.B.Borisenko, W., Li, G.Buckton, A,Stewart, A.I.Kirkland. ECM29 Croatia, 2015.
- 116) Conversion of nanosuspensions of dry powders by spray drying: a platform for the preparation of inhalation particles.

 M.Malamatari, M.Bloxham, S.Somavarapu and G.Buckton, J Aerosol Med and Pulmonary Del.

M.Malamatari, M.Bioxnam, S.Somavarapu and G.Buckton, J Aerosol Med and Pulmonary Del 28, A11, (21015).

10) Patents

Al-Hadithi, Buckton, Brocchini: Derivatised Particulate Inhalation Carriers: WO 03/094884

Al-Hadithi, Buckton, Brocchini: Particulate Inhalation Carriers: WO 02/45682

Fletcher, Buckton and Brocchini, Solid dispersions for oral drug release (filed January 2005)

(all lapsed)

Columbano, Buckton, Wickeley. Glycosides to stabilize inhalations granted patent

Patents granted from work at Pharmaterials Ltd for IntraCellular Therapeutics (but the text of which I have not been involved with and did not write) – US 61/838,105 :"Free base crystals" (2013) and WO 2014/205354

11) Research Supervision

PhD Research students supervised

- T.C.Blair. Some factors influencing the survival of microbial contaminants in solid oral dosage forms. SERC award: 1986-1989.
- N.Mitchard. The interactions of proteins and synthetic polymers with model hydrophobic drug carrier systems. Funded by ADDR Ciba-Geigy: 1987-1990.
- S.C.Forster. Changes in physical properties of an homologous series of solids. Funded by Glaxo Group Research: 1987- writing up.
- S.Russell. Title withheld. Funded by The Wellcome Foundation: 1988-1991.
- G.Parsons. The use of surface energies to model the stability of non-aqueous suspensions. SERC / CASE (Lilly Research Centre Ltd.): 1988-1991.
- A.MacKellar. Controlled crystallisation. SERC / CASE (Beecham Pharmaceuticals): 1988-1991.
- J.H.King. The effects of processing on the structure of ointments and creams. Funded by The Wellcome Foundation: 1988-1991 (did not submit).
- P.L.Sheridan. The use of computer modelling to predict the surface energies, and behaviour of powders. SERC / CASE (MSD): 1990-1993.
- J.F.A.Pinto. Development of novel controlled release products from pellets. Personal funding: 1990-1993.
- S.Mall. Surfactant interactions in solid dosage forms. SERC / CASE (MSD) 1992-1995
- D.Carthew. Stabilisation of microfine suspensions. Wellcome Foundation Ltd., 1992-1995.
- H.Ahmed. The influence of processing on material properties. SERC/CASE (MSD), 1993-1996.
- P.Darcy. Studies on the amorphous form of lactose. 1994-1998 (part time)
- P.Patel. Crystal structure determination and physico-chemical characterisation of salt forms of drugs. SERC/CASE (SB) 1994-1997.

- J.Dove. Molecular modelling, crystal structure determination and physico-chemical characterisation of a range of related drugs. Roche Products. 1994-1997.
- M.Ah-Fat. Modelling of powder mixing (1995-1998)
- R.Patel. Drug surfactant interations (1995-1998)
- O.Chidavaenzi. Understanding spray granulation (1995-1998)
- S.Ali, Suspension stabilisation, Glaxo-Wellcome (1996-1999)
- A.Shah, The influence of processing on powder crystallinity, MSD CASE (1997-2000)
- A.Colombano, Physico-chemical characterisation of novel surfactants, Astra, (1998-2001)
- S.Hogan, Stabilising protein formulation, RPSGB, (1998-2001)
- L.Barriocanal, Surfactant-macromolecule interactions, School Millennium Studentship, (1999-2002).
- M.Daifi, Spray drying processing, SB CASE award, (1998-2001)
- C.Galligan, The influence of surface energy on mixing. Pfizer, (1998-2001)
- J.Guaquiere, Novel particles for inhaled delivery of proteins, (1998-2001)
- R. M. Samra, Characterisation of Terfenedine and a model of hydrophobic amorphous Form of a drug and preparation and characterization of some of its derivatives, (part-time 1998-2003)
- R. Viboonkiat, Stabilising amorphous solid dosage forms (1999-2002)
- D. Al-Hadithi, Development of novel inhaled particles, Novartis (1999-2002)
- A. Moran, Solid state stability of macromolecular drugs, BBSRC, (2000-2003)
- E. Beusang, Modification of the surfaces of microparticles for inhalation drug delivery, AsraZeneca (2001-2004)
- L. Schueller, Dry powder inhalation: investigation of physical and chemical modifications of carrier on drug deposition, Novartis, (2001-2004)
- E. Mwesisgwa, The Hygroscopicity of Moisture-Barrier Film Coatings, Commonwealth Scholarship (2001-2004)
- K. Vora, Use of Dynamic Vapour Sorption Technique to Probe Surface Energies and Wettability of Powders, EPSRC CASE/GSK ((2001-2004)

- J. Stapely, The application of inverse gas chromatography (part–time 2003 2007) GSK funded.
- J. Fletcher, Studies of dispersion of drugs in polymers (EPSRC 2001-2004)
- A. Khalid, Studies of spray dried particles for stabilising proteins (EPSRC 2002-2005)
- A.Ambarkhane, Investigating into predicting the long term physical stability of amorphous compounds, GSK/SOP (2002-2005)
- M. Pollitt, (with Dr Brocchini and Prof Alpar) Nasal delivery of proteins SOP, (2003-2006)
- R. Ramos, The effect of milling process on crystalline drugs , Schering Plough, (2003-2006)
- C.V. Scaria, (with Dr Gaisford), Use of isothermal microcalorimetry for stability studies. SOP, (2003-2006)
- V. Gohil, Micronised/Milled Materials and Wet Granulation, AstraZeneca, (2003-2006)
- Z. Ding, Titration calorimetry to study surfactant interactions with drugs (2003-2006)
- L. He, Drug loading and release from hydrogels (2003-2006)
- A. Matos De Oliveira, Spray dried powders for dry powder inhalers, Pfizer (2004-2007)
- H Al-Obaidi, Griseofulvin in Solid Dispersions, (2004-2007)

Peng Ke, self funding (2005-2008) Stability of amorphous dispersions.

K. Barck, Astra Zenecca, studies on pMDI inhalation systems (2005-2008)

WangJing Li self funded (2010-2013). Stability of amorphous dispersions.

M Malamataris (2013-2016) EPSRC DTC grant. Engineering particles from nanoparticle association.

Visiting scientists

The following have worked in my laboratories:-

Dr L Zajic, University of Belgrade, Yugoslavia.; Dr M Efentakis, University of Athens, Greece; Dr L Oner, University of Hacettepe, Turkey; Dr M Angberg, University of Uppsala, Sweden; Mr C Tapia, University of Santiago, Chile; Dr S Tamburic, University of Belgrade, Yugoslavia; Dr E Papadimitriou, University of Athens, Greece; Ms T Gregori, University of Pavia, Italy; L Rousseau, University of Grenoble, France; V Ludet, University of Grenoble, France; Dr M Montagno Cappuccinello, Pharmacia Farmitalia, Italy; Dr M Rillosi, University of Pavia, Italy; Professor Ch'ng Hung Seng, Penang, Malaysia; Dr E O Machiste, University of Pavia, Italy; Dr

E Yonemochi, Chiba University, Japan; Dr O Planinsek, University of Ljubljana, Slovenia; Dr M Ohta, Meiji Seika Kaisha Ltd, Japan; Dr M Ono, Daiichi Pharmaceutical Co. Ltd., Japan; Dr M Makoto Seiki Pharmaceuticals Japan, Dr Susumu Hasegawa, Sankyo Co. Ltd., Japan.

12) Invited and external lectures SINCE 2001

- 1) Plenary lecture at Krka award ceremony, Slovenia, January 2001
- 2) Research seminar Vectura Ltd, March 2001
- 3) Lecture at Swedish APS 4th International Symposium on Solid Dosage Forms, May 2001
- 4) Plenary lecture EUFEPS meeting on solid dosage forms, May 2001
- 5) Presentation at 29th Interpharm Research Conference, May 2001
- 6) RPSGB meeting Physical stability testing lecture, May 2001
- 7) Seminar Petra University Jordan, May 2001
- 8) Management Forum speaker Dry powder inhalers, powder properties, June 2001
- 9) Plenary lecture 1st World Conference on Inverse Phase Gas Chromatography, September 2001
- 10) Plenary speaker EUFEPS 10th Anniversary conference, September, 2001
- 11) Invited lecture at Technology Showcase, BPC, September 2001
- 12) Invited speaker, Drug delivery symposium, Edinburgh (Quintiles), September 2001
- 13) Management Forum Physical form of excipients with regard registration, September 2001
- 14) Invited presentation at AAPS Denver USA, October 2001
- 15) Invited seminar Bristol MS New Jersey USA, October 2001
- 16) Six lectures to RPSGB Tabletting Course, November 2001
- 17) RPSGB stability testing, April 2002
- 18) Seminar Strathclyde University, May 2002
- 19) Seminar Mahidol University, Bangkok, August 2002
- 20) Management Forum Excipients -regulatory issues, September 2002
- 21) BPC Presentation on Inverse Phase Gas Chromatography, September 2002.

- 22) Presentation at AAPS "Excipioeconomics" October 2002.
- 23) Schering Plough New Jersey, Seminar October 2002
- 24) RPSGB meeting on Tabletting Technology. Series of lectures. Cambridge, November 2002.
- 25) IPEC Europe Seminar Plenary lecture Analytical Characterisation of Excipients, January 2003.
- 26) APS Inhaled Delivery Symposium, session chair and discussion group leader.
- 27) Materials Department, QMW University of London, seminar Physical properties of materials of importance for drug delivery, February 2003.
- 28) RPSGB Stability Testing, Cambridge, April 2003.
- 29) Invited presentation to the London, Oxford and Cambridge joint show case of leading new biotech companies, for Pharmaterials Ltd.
- 30) Swedish APS Presentation on Characterisation and quantification of amorphous content in excipients, September, 2003.
- 31) BPC Science Conference Chairman, September 2003.
- 32) Management Forum Excipients Conference Presentation on Physical Testing of Excipients to Ensure Functionality, London, September 2003.
- 33) Kings College London Seminar on Physicochemical Characterisation of Importance for Drug Delivery. October 2003.
- 34) British Crystallographic Association Industrial Group, Invited lecture on Amorphous Materials, November 2003.
- 35) RPSGB Course Director for meeting on Tabletting Technology. Cambridge, November 2003.
- 36) Management Forum Speaker on Physical impurities and their effect London, February 2004.
- 37) RPSGB Stability Testing, Cambridge, February 2004.
- 38) International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology Co-Chair and speaker Pharmaceutical materials to underpin Drug Delivery, Nuremberg, March 2004.
- 39) Interpharm Research Conference IGC to determine the surface Tg of particles. Chester. May 2004
- 40) Seminar at Bespak on Pharmaceutical Materials Science. July 2004

- 41) In-house training course on physical form Sanofi-Aventis, September 2004
- 42) Hyper DSC and Inverse Gas Chromatography British Pharmaceutical Conference Manchester, September 2004
- 43) Thermal methods to characterise the solid state EDQM Quality on the Move: Dynamics of the European Pharmacopoeia. Budapest, October 2004.
- 44) Workshop on the amorphous state (IQWPC) Frankfurt, October 2004
- 45) Symposium to mark the retirement of Henning Kristenson, Copenhagen, October 2004.
- 46) Web cast organised by Perkin Elmer- Applications of Hyper DSC November 2004
- 47) Seminar Materials Properties to underpin Drug Delivery, Astra Zeneca, Wilmington USA November 2004.
- 48) RPSGB Tabletting Technology, series of lectures, November 2004
- 49) Training conference on Poorly Soluble Drugs series of lectures, London November 2004
- 50) Physical characterisation of materials and the significance for drug delivery Plenary lecture to Korean Pharmaceutical Conference November 2004
- 51) Pharmaceutical materials science. Chuncheon University, Korea November 2004
- 52) Physical form and its significance for drug delivery. Active Biotech, Lund Sweden, December 2004
- 53) Surface properties of powders, determination and application (2 lectures) AAPS Arden House, Harriman NY, January 2005.
- 54) Amorphous materials where are we now and where will we go? APSGB Amorphous Materials, London February 2005.
- 55) Physical impurities. Management Forum, Barcelona, March 2005
- 56) Hyper DSC, Seminar to global Pfizer sites through video conference, March 2005
- 57) Solid dispersions and the amorphous state. Arden House Conference, London, March 2005
- 57) Inverse gas chromatography. Arden House Conference, London March 2005
- 58) Inverse gas chromatography. Novartis Pharma, Basle, April 2005
- 59) Respiratory Drug Delivery Europe, Amorphous content control Feasible test methods and specifications for inhaled drug products. Paris, May 2005 (Plenary)
- 60) Amorphous content control a review of test methods GSK Ware in house seminar. July 2005.

- 61) Pharmaterials four years on. BPC Technology Showcase, Manchester, September 2005.
- 62) Physical characterization for product development. Dr Reddy's, Hyderabad, India, August 2005.
- 63) Amorphous Materials detection, quantification removal and stabilization. IRR Optimising Polymorph Selectionand Crystallisation Processes. London 22-25th November (also meeting Chairman for the entire event). London, 22-25 November 2005
- 64) RPSGB Tabletting Technology series of lectures. November 2005
- 65) Importance of Physical Form for Product Development and Life Cycle Management Japan, December 2005
- 66) London Technology Network London, January 2006
- 67) Stability Testing Characterising Materials With Respect to Physical Stability Cambridge, February 2006.
- 68) Management Forum The Impact of Small Physico-Chemical 'Impurities' on Product Performance Barcelona, March 2006.
- 69) Pharma IQ Polymorphism & Crystallisation 2006 Amorphous Behaviour Workshop, London, March 2006.
- 70) TAC Thermal Methods for Process Induced Disorder London, April 2006.
- 71) IWPPCAS-1 Presented talk and chaired session Stamford, May 2006.
- 72) Amorphous Meeting Ran and delivered programme for 2 day training course, London, 7 June 2006
- 73) European Continuing Education College Formulation and Development for Poorly Water Soluble Drugs London, June 2006.
- 73) Impurities Meeting IPC Effectively Overcoming the Consequences of Polymorphism in the Production of Your APIs London, June 2006.
- 74) Webcast on the use of Hyper DSC 12 October
- 75) Poorly Soluble Drugs Ran and delivered a two day course. London 18/19 October 2006
- 76) AAPS Short Course. "Compatability starts at the interface" at AAPS Annual Conference Venue 29 October 2006
- 77) Amorphous materials course. Ran and delivered a 2 day course. Copenhagen 16 / 17 November 2006.
- 78) RPSGB Tabletting Technology. Delivered a series of lectures. 27 November 2006

- 79) JPAG "Functionality testing of excipients and APIs" London 7 December 2006
- 80) 7th Int. Symp. On Drug Delivery. CRS Inidian Chapter, Mumbai, 13 February 2007. Plenary lecture.
- 81) Poorly soluble drugs course, European Continuing Education College, London 19 March 2007 (3 hour lectures)
- 82) JPAG meeting "Characterisation of Amorphous Materials" London, 22 March 2007
- 83) APS Inhalation "Problem solving and decision making in inhaled drug delivery" 27th March 2007 Bath.
- 84) Astra Zeneca symposium on poorly soluble drug substances. Loughborough 29 March 2007. "Advances in amorphous formulations".
- 85) Management Forum "The impact of small physico-chemical impurities on product performance". Nice, 27 April 2007.
- 86) NATAS, Michigan, 26/27 August 2007

Presented 2 short courses, one plenary lecture and co-hosted session on Pharmacy:

"Isothermal, solution and titration calorimetry to study pharmaceutical systems" Short course

"Hyper DSC and its potential" Short course

"Characterising the amorphous state" Plenary Lecture

- 87) Management Forum "The impact of small physico-chemical impurities on product performance". Nice, 5 October 2007
- 88) Pharmaceutical Training Services Amorphous Conference. London,11/12 October 2007
- 89) Society for Pharmaceutical Medicine "Changes in drug delivery over 20 years". London, 25 October 2007
- 90) RPSGB, Tabletting Technology presented the following courses:
- "A review of the reasons for granulation and tabletting, the classes of excipients and principles of operation of tabletting machines"

"Material Properties of Importance for Tabletting (I) and (II)"

"A Brief Introduction to Modified Release"

Cambridge, 19 November 2007

91) Seminar at Boehringer Ingleheim, January 2008

- 92) 3rd SAB Meeting, Mumbai, 22-25 Feb 2008, 'Physical Form and its Significance for Drug Delivery',
- 93) FMC Florida, 27-29 Feb
- 94) APS Amorphous Conference, Bath, 18/19 March 2008, 'The Future of Amorphous Materials'
- 95) Impurities Conference, 'The Impact of Small Physico-Chemical "Impurities" on Product Performance', Nice, 10/11 April 2008
- 96) Colourcon, 'Poorly Soluble Drug Formulation', 30 April 2008
- 97) AAIPS, Washington, 8 May 2008
- 98) Interpharm, 'New Trends in the Pharmaceutical & Regulatory Sciences', 3-6 May 2008
- 99) Cambridge Seminar, 3 June 2008
- 100) Pharma Event ASSA International Workshop 'Particle Characterisation' July 2008
- 101) Informa Life Sciences meeting Crystal Form Selection and Crystallisation of API 'Choosing an amorphous phase over a crystalline phase', Brussels, 14 October 2008
- 102) Colorcon Formulation School, Germany, 6 November 2008
- 103) ECEC Course Formulation and Development of Poorly Water-Soluble Drugs 'Solid dose strategies for poorly water soluble drugs', London, 11 November 2008
- 104) Colorcon Formulation School, Budapest, 12 November 2008
- 105) RPSGB, Tabletting Technology series of lectures. 24 November 2008
- 106) Drug Delivery to the Lungs 'Academic/Industry/Spin out Interactions Drivers for Inhalation Innovation', Edinburgh, 11 December 2008
- 107) 4TH Scientific Advisory Board Meeting seminar given on 'Amorphous Pharmaceuticals', Mumbai, 23 February 2009.
- 108) Controlled Release Society (CRS) Indian Chapter lecture given on 'Amorphous Pharmaceuticals', Mumbai, 25 February 2009.
- 109) Interpharm (Chairman of meeting) The challenges facing pharmaceutical science in the UK. Careys Manor 13-15 May 2009.
- 110) Management Forum Impurties meeting, Series of lectures, Nice, 25-26 June 2009.
- 111) Workshop on Inhalation, Informa Life Sciences, London 21 Sept 2009.
- 112) Compiling a physic-chemical profile (for inhalation products) Informa, London, 22 Sept 2009.

- 113) Short course in poorly soluble drug formulation, Teva, Israel, 25-26 November 2009.
- 114) Solid dispersions: Ideal if the formulation and process are right. APS Amorphous 2010. Nottingham 14 h April 2010.
- 115) Interpharm 2010 (Chairman of Meeting), talk "Ordered Chaos". Careys Manor, Hampshire, May 2010.
- 116) Characterisation of amorphous dispersions. Informa Meeting Slovenia, 18th May 2010.
- 117) Finding the optimum polymorph strategy. Bio2Business, Copenhagen, 17th June 2010.
- 118) Amorphous pharmaceuticals. Visiongain. London. 24th January 2011.
- 119) Series of 3 lectures on physical form, testing methodology and excipient compatibility. Impurities. Management Forum, London 10th June 2011.
- 120) Early formulations: selecting a strategy to achieve fast to man. Bio2Business London, 20th Sept 2011.
- 121) A strategy for formulation of poorly soluble APIs. AAPS Annual Meeting., Washington DC. 25th Oct 2011.
- 122) RPSGB Tableting Technology series of 5 lectures, November 2011 London
- 123) RPSGB Tableting Technology series of 5 lectures, November 2012 London
- 124) Poorly soluble drug delivery Society for Medicines Research, London, October 2012.
- 125) Thermal studies of physical form Thermal Methods Conference, Hertfordshire, November 2012.
- 126) Update on physical form. Allergan, California, June 21013.
- 127) RPSGB Tableting Technology series of 5 lectures, November 2013 London
- 128) Interpharm conference Overview presentation May 2014, Midlands, UK
- 129) Update on poorly soluble drug delivery. Allergan, California, June 2014
- 130) RPSGB Tableting Technology series of 5 lectures, November 2014 London
- 131) RPSGB Tableting Technology series of 5 lectures, November 2015 London

13) Expert witness

I list below the cases which have progressed to trial or public hearing in which I have assisted as an expert witness. I have underlined the company for which I was retained.

- 1) UK written evidence, settled at court GSK v Generics UK. Paroxitene hydrate form. [2001]
- 2) Deposition USA GSK v <u>Teva</u>. Rosiglitazone maleate salt form. [2007]
- 3) Dublin, court testimony. GSK v <u>Norton Healthcare (Teva)</u>. Seretide inhalation formulation patent. [2009] IEHC 277 Dublin.
- 4) UK court testimony. <u>Schering Plough</u> v Norbrook. Sustained release veterinary product [2005] EWHC 2532 (Ch) London
- 5) Deposition USA December 2009. <u>Duramed</u> v Paddock. Sustained release tablet formulation.
- 6) Sweden 2010 written declaration. Cepahalon v <u>Orifarm</u>. Modafinil formulation (particle size).Odense, Denmark, December 2010. Infringement hearing. Cephalon v <u>Orifarm</u>. Modafinil formulation patent. UK report preliminary injunction. 2011. Cephalon v Orifarm / Orchid / Mylan (Generics UK). Modafinil formulation patent. Danish Appeal Court testimony September 2011, Cephalon v <u>Orifarm</u>. Modafinil formulation patent.

UK court testimony – May 2011. Cephalon v <u>Mylan(Generics UK)</u> / Orchid. Modafinil formulation patent.

- 7) UK court testimony February 2011. Schering (Bayer) v <u>Gedeon Richter</u>. Oral contraceptive (drospirenone and ethinyl estradiol) tablet formulation.
- 8) US court testimony June 2011 Valeant v <u>Watson</u>. Bupropian HBr salt patent (deposition in December 2010)
- 9) Deposition USA October 2011, Warner Chilcott v Mylan. Doryx formulation. Court testimony February 2012, Warner Chilcott v Mylan. Dorxy formulation (stabilizing coat patent). Newark, New Jersey.
- 10) Deposition May 2013, <u>Par</u> v Novartis, Rivastigmine transdermal patch. New York. And also Deposition in same case in August 2013 and April 2014. Trial testimony in the same case May 2014 in Wilmington Dellaware.
- 11) Deposition Oct 2013, Mylan (Lupin) v Janssen, Darunavir tablets. Chicago. USA.
- 12) Deposition August 2014, <u>Watson</u> (Actiavis) v Sepracor (Sunovion), Levalbuterol tartrate MDI. Washington DC. Trial in same case November 2014 Willmington Dellaware.
- 13) UK Court testimony. <u>Teva</u> v Boehringer Ingelheim. Tiotropium bromide inhalation capsules. July 2015. Norway court testimony on the same case March 2016.
- 14) Deposition July 2015. Apotex (consolidated with Sandoz, Alembic, Zydus, Intas and Hetero) v Otsuka Aripiprazole low hygroscopicity forms. Follow up deposition Washington DC, Sept 2015, same case. Testimony at the Markman hearing in Camden New Jersey, October 2015.

- 15) Deposition July 2015 Rufinamide polymorphs. <u>Roxane, Mylan, Lupin</u> v Novartis. Deposition.
- 16) Deposition October 2015 <u>Perrigo</u> v AstraZeneca, Esomeprazole trihydrate claim construction.
- 17) Trial testimony, February 2016, Bayer v <u>Cobalt.</u> Drospirenone / ethinyl estradiol tablet. Toronto, Canada.
- 18) UK Court testimony, June 2016, <u>Actavis / Teva / Mylan / Actelion</u> v ICOS / Lilly. Tadalafil particle size formulation patent.
- 19) Deposition July 2016, Mylan v Noven, Methylphenadate transdermal patch claim construction.